

RLL-297US

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Listing of Claims:

1. (Original) An amorphous form of a salt of esomeprazole.
2. (Original) The amorphous form of a salt of esomeprazole of claim 1, wherein a cation is selected from the group consisting Na, Mg, Li, K, Ca, and N(R)₄, where R is a hydrogen or an alkyl group with 1-4 carbon atoms.
3. (Original) The amorphous form of a salt of esomeprazole of claim 2, wherein the cation comprises Na.
4. (Original) The amorphous form of a salt of esomeprazole of claim 2, wherein the cation comprises Mg.
5. (Original) The amorphous form of a salt of esomeprazole of claim 2, wherein the cation comprises K.
6. (Original) The amorphous form of a salt of esomeprazole of claim 2, wherein the cation comprises Ca.
7. (Previously Amended) The amorphous form of a salt of esomeprazole of claim 1, wherein the esomeprazole salt has the X-ray diffraction pattern of a plain halo.
8. (Cancelled).
9. (Original) A pharmaceutical composition comprising:
a therapeutically effective amount of an amorphous form of a salt of esomeprazole;
and one or more pharmaceutically acceptable carriers, excipients or diluents.
10. (Original) The pharmaceutical composition of claim 9, wherein a cation is selected from the group consisting of Na, Mg, Li, K, Ca, and N(R)₄, where R is a hydrogen or an alkyl group with 1-4 carbon atoms.
11. (Original) The pharmaceutical composition of claim 10, wherein the cation comprises Na.
12. (Original) The pharmaceutical composition of claim 10, wherein the cation comprises Mg.
13. (Original) The pharmaceutical composition of claim 10, wherein the cation comprises K.

14. (Original) The pharmaceutical composition of claim 10, wherein the cation comprises Ca.
15. (Previously Amended) The pharmaceutical composition of claim 10, wherein the esomeprazole salt has the X-ray diffraction pattern of a plain halo of Fig. 1.
16. (Cancelled)
17. (Original) A process for the preparation of a salt of the amorphous form of esomeprazole, the process comprising:
- preparing a solution of a salt of esomeprazole in one or more solvents; and
- recovering the salt of esomeprazole in the amorphous form from the solution thereof by the removal of the solvent.
18. (Original) The process of claim 17, wherein a cation is selected from the group consisting of Na, Mg, Li, K, Ca, and N(R)₄, where R is a hydrogen or an alkyl group with 1-4 carbon atoms.
19. (Original) The process of claim 18, wherein the cation comprises Na.
20. (Original) The process of claim 18, wherein the cation comprises Mg.
21. (Original) The process of claim 18, wherein the cation comprises K.
22. (Original) The process of claim 18, wherein the cation comprises Ca.
23. (Original) The process of claim 17, wherein the solvent comprises one or more of lower alkanol, ketone, ester, chlorinated solvent, acetonitrile or mixtures thereof.
24. (Original) The process of claim 23, wherein the lower alkanol comprises one or more of primary, secondary and tertiary alcohol having from one to six carbon atoms.
25. (Original) The process of claim 23, wherein the lower alkanol comprises one or more of methanol, ethanol, denatured spirit, n-propanol, isopropanol, n-butanol, isobutanol, and t-butanol.
26. (Original) The process of claim 23, wherein the lower alkanol comprises one or more of methanol, ethanol, and denatured spirit.
27. (Original) The process of claim 23, wherein the ketone comprises one or more of acetone, 2-butanone, and 4-methylpentan-2-one.

28. (Original) The process of claim 23, wherein the ester comprises one or more of ethyl acetate and n-butyl acetate.
29. (Original) The process of claim 23, wherein the chlorinated solvent comprises one or more of chloroform and dichloromethane.
30. (Original) The process of claim 17, wherein removing the solvent comprises one or more of distillation, distillation under vacuum, evaporation, spray drying, and freeze drying.
31. (Original) The process of claim 17, wherein the salt of esomeprazole in an amorphous form is recovered from the solution by spray drying.
32. (Original) The process of claim 17, wherein the salt of esomeprazole in an amorphous form is recovered from the solution by freeze-drying.
33. (Original) The process of claim 17, further comprising additional drying of the product obtained.
34. (Original) The process of claim 17, further comprising forming the product obtained into a finished dosage form.
35. (Original) The process of claim 17, further comprises adding one or both of an organic amine and ammonia to the solution.
36. (Original) The process of claim 36, wherein the organic amine and/or ammonia is added to the solution prior to removal of the solvent.
37. (Previously Amended) The process of claim 17, wherein the amorphous esomeprazole salt obtained has the X-ray diffraction pattern of a plain halo Fig-1.
38. (Cancelled).